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IN THE
# Supreme Court of the United States

WILLIAM J. CATALONA, PETITIONER

*v.*

WASHINGTON UNIVERSITY, RESPONDENT.

RICHARD WARD, *ET AL.*, PETITIONERS

*v.*

WASHINGTON UNIVERSITY, RESPONDENT.

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT*

## BRIEF OF *AMICUS CURIAE* US TOO, INTERNATIONAL IN SUPPORT OF PETITIONERS

ROBERT S. ADLER
*ROBERT S. ADLER, PC*
*7777 Bonhomme Avenue*
*Clayton, Missouri 63105*
*(314) 725-2400*

*Counsel for Amicus Curiae Us TOO, International*

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## INTRODUCTION

## INTEREST OF AMICUS

***Amicus Curiae Us TOO International*** respectfully submits this brief under Rule 37.[1]

***Us TOO International*** is a prostate cancer support organization founded in 1990 by prostate cancer survivors to serve prostate cancer patients and their families. ***Us TOO International*** is a network of 325 support groups located in the United States (U.S.) and 10 countries made up of thousands of prostate cancer health care professionals, patients, survivors and their family members who work as volunteers to share education, information and support in the battle against prostate cancer. ***Us TOO International*** is the only prostate cancer organization whose exclusive mission is to be the voice of patients. Other organizations, like the American Cancer Society, represent patients in some settings, but have conflicts of interest about representing patients in this case since they conduct research and run biorepositories.

***Us TOO International*** is a 501(c)(3) not-for-profit charitable organization dedicated to communicating timely and reliable information

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[1] No counsel for a party authored this brief in whole or in part; no person other than amicus or its members made a monetary contribution intended to fund the preparation or submission of this brief. Timely notice of intent to file this brief was given to all parties, and all parties provided written consent to the filing of this brief.

enabling informed choices regarding detection and treatment of prostate cancer. It also provides information about the potential risks and benefits of participating in clinical research. ***Us TOO International*** is committed to enhancing the quality of life for all people affected by prostate cancer.

The primary mission of the ***Us TOO International*** advocacy effort is to identify, enlist and support a national team of prostate cancer volunteer advocates from the core of men with prostate cancer, their friends and loved ones and concerned others, including physicians and scientists to carry out the mission of the organization. Our members have participated in the studies at Washington University and in other research studies. The effects of this case - including the 8th Circuit's abrogation of the federal protections designed to protect patients who participate in research - are devastating to participants and to research, and it is of vital importance to the research participants that the law should be correctly applied.

The goal of prostate cancer research is to eliminate or reduce suffering and death from prostate cancer. While there is evidence that participating in prostate cancer research can save lives, there will be no research without the participation of the people who provide their time and literally themselves.

A prime example of research that was made possible through the voluntary participation of men like Petitioners Ward, McGurk, Garcia, Castro, Parron, Wiland, Ellis, and Missios is the early

detection of prostate cancer through testing of blood samples for prostate specific antigen (PSA). This research was pioneered by Dr. Catalona beginning in 1991. Since this time, there has been more than a 75% reduction in the proportion of patients who have advanced metastatic disease at the time of prostate cancer diagnosis in the U.S. through 2003, and a 32.5% reduction in the age-adjusted prostate cancer mortality rate according to the National Cancer Institute (website: http://www.seer.cancer.gov/statfacts/html/prost.html ?statfacts_page=prost.html&x=10&y=14).

A study examining the relation of PSA screening to the stage of cancer at diagnosis and prostate cancer death rates in 30 population-based U.S. cancer registries revealed that the more prevalent the PSA testing in a region of the U.S., the less advanced-stage disease is diagnosed and the lower the prostate cancer death rate (Jemal A et al, Cancer Epidemiol Biomarkers Prev 2005;14:590). This research would not have been possible without men who had been diagnosed with prostate cancer, and their families, voluntarily agreeing to participate in prostate cancer research studies.

The progress made in prostate cancer research in the future will be in genetics. New advances in genetics have lead to the now-frequently used term, "Personalized Medicine," referring to the treatment of cancer and other diseases depending to some extent on the patient's personal DNA (reviewed extensively in May of 2006 in the journal *Science* (*Frontiers in Cancer Research*, Special Content, 312 *SCIENCE* 1162-1178 (May 26, 2006)). Because this

kind of research will determine future directions for cancer care, ***Us TOO International*** has a highly vested interest in preserving patient trust and confidence in the research community in this country. As will be shown below, most adults in the U.S. do not believe current law and organizational policies provide them enough privacy protection in medical research.

Accordingly, the voice of ***Us TOO International*** is important in this compelling landmark case, which has been wrongly decided in the courts below. This case is a critical test, because unless these protections are accorded every patient and research participant, people will become unwilling to volunteer for research.

***Us TOO International*** submits this brief as *amicus curiae* for the purpose of bringing new matters to the Court to assist it in making its decision concerning the petitions for writ of certiorari on this issue of great national importance.

## SUMMARY OF ARGUMENT

The first inviolable principle of human research is that participation must be voluntary and consent must be informed. People have the right to choose, or to decline, to participate in research. And people have strong feelings – ethical, moral, religious - about the types of research they are willing to participate in. The federal regulations codify participant's rights in research by reiterating that consent must be voluntary and informed and that participants have the right to discontinue

participation at any time for any reason. 45 C.F.R. §§ 46.116, 46.116(a) (8).

The lower court's finding, and Washington University's argument that it can continue to perform research on the tissue of a person who has withdrawn from research merely by taking the person's name off the sample is preposterous. Continuing research on the tissue violates a person's right to not be researched upon without their consent. Stripping a person's name off a tissue sample does not change the unique genetic makeup of the sample that could only have come from that one person.

## STATEMENT OF FACTS

Petitioners are William J. Catalona, M.D. of Illinois, and Richard N. Ward of Kansas, Thomas A. McGurk of Indiana, Luis Garcia, Antonio Castro, and Ivan Parron of Florida, Philip Wiland of Colorado, James D. Ellis of Texas, and Mike Missios of Alabama. All patient petitioners are former patients of Dr. Catalona.

Dr. Catalona, a preeminent prostate cancer surgeon and researcher, played a leading role in the development of a large tissue bank while he was employed at Washington University. The patients who are petitioners in this suit, all non residents of State of Missouri, enrolled in research protocols designed by Dr. Catalona while he was an employee of Washington University, and all provided tissue as part of their participation in his research protocols. They, along with the 6,000 other people who wrote

Washington University, are unanimous in their desire for Dr. Catalona, not Washington University, to conduct further prostate cancer research on their tissue – as they were initially promised.

These patients each had their cancerous prostate gland removed by Dr. Catalona and consented to participate in research allowing testing to be performed upon their retained prostate tissue and blood samples by Dr. Catalona and his collaborators. Each participant typically was asked to sign both a consent form and an informational brochure that Washington University had provided, frequently right before surgery was performed. While some of the consent forms referred to the provision of samples as a "donation," they also promised the research participant that he could discontinue participation or withdraw consent at any time. The informational brochure provided to participants stated that a research participant could change his mind and ask that his samples no longer be used in research or even be destroyed.

The consent forms also provided information about the risks the patients and their families faced by participating in genetics research, such as the risk of discrimination in insurance and employment if insurers or employers were to find out information revealed in the study. Because of these risks, it is of vital importance that the research participants maintain continued control over what is done with their tissue and that the University be forced to follow rules governing the participation of human research subjects, as well as the express promises made to the participants.

Currently, the personal identities and protected health information are linked to the samples the participants provided in electronic research databases. Not only is this the most valuable method for research purposes, it also creates the most risk for the participants that their confidential information will be disclosed.

Early in 2003, the participants requested in writing that Washington University transfer their tissues to Dr. Catalona, now at Northwestern University, for continuation of the prostate cancer research they desired to be performed. They are among 6,000 other patients and research participants who sent written requests to Washington University seeking to have Dr. Catalona have custody of their samples for purposes of continuing the research that they originally intended and for which they consented. Washington University did not inform the research participants who provided their tissue to be used in research studies that their tissue was now the subject of a lawsuit and in fact objected to the research participants' motion to intervene in the case. Because the University and its ***amici*** do not speak in the patients' interest, the voice of ***Us TOO International*** is crucial to this case.

The federal district court's and the subsequent 8th Circuit Court of Appeals' decisions failed to consider the proper impact that federal regulations and the Common Rule have upon the Missouri state law under consideration. This failure to accede to the power of the higher federal authority violates the

established principle that the Supremacy Clause invalidates state laws that obstruct federal law. U.S. Const. art. VI, cl. 2, *Hillsborough County v Automated Med. Labs, Inc*, 471 U.S. 707,712,713 (1985). See *Geier v. American Honda Motor Co.*, 529 U.S. 861, 884 (2000); *Long Island Care at Home, Ltd. V. Coke*, 127 S. Ct. 2339, 2349 (2007). It is of vital importance to the integrity of the U.S. research enterprise that this sidestepping of the federal issue by these lower courts be addressed by the Supreme Court.

The Judgment in this case makes no distinction between human subjects' bodily tissues and fungible goods. The tissues and blood involved here are not fungible goods[2]. Each is linked to the research subject, and is identifiable and unique. The district court, affirmed by the 8th Circuit, held that Washington University owns the human tissue, including Petitioners' tissue, held in the biorepository. Such a decision ignores the controlling federal regulations and is based upon language that is not permitted by federal regulations.

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[2] The University has argued that the patients providing the tissue is like them giving money to a charity, where they cannot direct how it is used after the charity receives it. This exemplifies how little respect the University has for the patients' tissue and their private genetic information contained therein. While money has no memory, the patients' tissue contains highly personal information about them, their ancestors, and their descendents.

## ARGUMENT

Patient and research participant rights and protections are a significant and pervasive issue of concern among the American public that has not been fully addressed by either of the petitions before this Court, and there are compelling reasons for the Court to grant full review.

The courts' decisions below show confusion and a misunderstanding of the research enterprise in this country. Human research is a multi-billion dollar industry in this country. But unlike other industries, it relies on people and their body parts for the raw material. People altruistically provide their tissue to be used in studies that are important to them. They are protected by the principle that research cannot be conducted upon them without their consent. Their right to informed consent also means that they have the right to choose which research studies they participate in. Research participants have inviolable rights to choose what research they are willing to allow on themselves and their tissue and to withdraw from research at any time for any reason (or for no reason at all). 45 C.F.R. § 46.116 (regarding informed consent); 45 C.F.R. § 46.116(a)(8) (regarding right to discontinue participation in research). These principles have been abrogated by the lower courts' decisions.

The purpose of the federal regulations known as the "Common Rule" is to protect people from abuse. People have strong feelings about what types of research should be done on them. Some individuals have religious beliefs about what

research should be done; for example, some people oppose embryonic stem cell research and would not want their tissue used in that research. In a study published in 2004, researchers found that 82% of survey respondents would be willing to donate tissue samples for cancer research; 65% would be willing to donate tissue samples for research on genetic disorders; 59% would be willing to donate tissue samples for research on general knowledge of tissues or for testing different medicines; and only 26% would be willing to donate tissue samples for research on genetic cloning.[3] In the same study, 42% of respondents wanted to be informed if their tissues were to be stored beyond the time required for diagnosis, and 35% wanted to be consulted if additional research was to be undertaken on stored tissue in the future.[4]

The evidence that people do care about the type of research they participate in, who performs the research, and what is done with their information is further buttressed by a recent study conducted by a prestigious non-profit organization, the Institute of Medicine (IOM). (www.iom.edu). In 2007, the IOM commissioned Harris Interactive, one of the most respected independent opinion polling services in the U.S., to conduct a poll to determine, among other things, how the public views the overall health privacy scene. More specifically, they set out to learn: (1) what kind of notice and consent the

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[3] Michael L. Goodson, B.G. Vernon, "A Study of Public Opinion on the Use of Tissue Samples from Living Subjects for Clinical Research," 57 Journal of Clinical Pathology 135-138, 137 (2004).

[4] *Id.* at 136.

public wants before their personal medical and health information is used in a study, and (2) what kind of privacy harms worry those who want to have express notice and consent before their private information is used in health research. Of people who have been asked to have their personal medical information used in research and decided *not* to participate, 30% were concerned that their personal medical information would not be kept private or confidential, while 22% did not have trust in people or organization that conduct the research. Practically none (1%) said that researchers would be free to use their personal medical information without their consent. No more than 19% said their consent would not be needed as long as their information was "de-identified." Thirty-eight percent of people would want each research study seeking to use their personal medical information to first get their specific consent.

The Harris poll and other studies plainly show how important it is that current regulations be enforced. As this case now stands, in the aftermath of the lower courts' rulings, after an institution has taken possession of the sample, ***no consent*** would be required for a research institution to conduct other unsanctioned research with it. This flies in the face of the first inalienable principle of human subject research that consent must be informed and voluntary. By ignoring the explicit language of the informed consent documents and the federal regulations, the court has created a precedent that regardless of what is promised to induce people to participate, the institution can later claim ownership of people's tissue. Regardless of what the consent

form said, the bottom line would be that the research institution (in this case Washington University) would own the samples.

Awarding Washington University ownership of the research participants' tissue forces them to participate in research without their consent. The research participants chose to participate in research to benefit themselves, their families, and society. They decided that the best way to accomplish this was to provide their tissue to be used by Dr. Catalona in his research studies. They do not want their tissue used by Washington University, even if their name is taken off the sample, which the university claims will "anonymize" it.

Anonymization of the research participants' samples at Washington University's discretion was an option created *post hoc* to allow it to continue research after a participant withdrew from research.[5] Incredibly, the district court adopted this argument and held that if the participants withdrew, Washington University, at its sole discretion, could remove all personal identifying information from the samples and use them for other research projects not approved by the participants. However, because of current technologies, it is never possible to truly anonymize a person's genetic sample and the possibility of a person being identified through their tissue is becoming a concern for researchers worried about the privacy of people who participate in research protocols. This concern

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[5] Plaintiff's Post-Hearing Reply Brief at 5.

is magnified as data and samples are increasingly shared and the federal government has begun mandating online posting of research data and results. (See Amy L. McGuire and Richard A. Gibbs, "No Longer De-Identified," 312 Science 370-71 (2006); Zhen Lin, Art Owen, and Russ Altman, "Genomic Research and Human Subject Privacy," 305 Science 183 (2004).) This year, a child was able to track down his anonymous biological sperm donor father by using his own DNA and online genetic genealogy resources. (Alison Motluk, *Anonymous Sperm Donor Traced on Internet*, Newscientist.com, November 3, 2005, http://www.newscientist.com/article.ns?id=mg18825244.200) Clearly a person's DNA cannot be "anonymized."

In any event, even attempted anonymization or de-identification goes against the research participants' intent, and diminishes the value of the tissue for research and the possible future benefit for the patient and his family. When the person's identity is linked to the sample, the person can be contacted for further information about his health. His samples can be linked to those of his relatives to try to identify genetic mutations that lead to particular diseases. Destroying the code linking the subject's name and relating information from the database would preclude or impede the research participant and his children from personally benefiting from the research. This negates one of the few benefits to the research participant noted in the informed consent documents, the idea that the research could specifically benefit the participant

and his family, including warning them of their risk of developing cancer.

Moreover, research on tissue creates psychological and financial risk for people. For example, people have lost their health insurance based on their participation in genetic research.[6] This is another reason people must be allowed to choose which research they will participate in and must be allowed to effectively withdraw from research.

Only by upholding these principles will research continue successfully in the future. People are already hesitant to participate in research. If allowed to stand, the court's judgment below will inhibit future medical research because patients will not agree to participate in studies when they learn that promises made to them in informed consent documents can be disregarded. They also will not participate in research if they have no control over who has their tissue, how that tissue is used, and what types of research are performed on their tissue. Taking this one step further, it is even possible that people will not seek out medical care if they cannot trust that their tissue will not be taken and used in medical research against their will. This is especially a concern for minority individuals, who have been shown to be less likely to seek medical care for existing conditions due to apprehension about what an institution will do with their tissue.

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[6] National Human Genome Research Institute. "Genetic Discrimination Fact sheet" <http://www.genome.gov/10002328>.

Rayna Rapp, *Refusing Prenatal Diagnosis: The Uneven Meaning of Bioscience in a Multicultural World*, 23 Sci., Tech., and Human Values 45 (1998).

Word of this case is already spreading. Even before this Court has made a determination on the Petitions before it, attorneys for Washington University's ***amici*** are publicly stating that institutions that conduct tissue research "are well advised to review informed consent forms and communications to research participants for consistency with state gift law and other applicable law."[7] According to a 2003 report issued by the Rand Corporation, large research universities including ***amici*** supporting Washington University below allow tissue sources to withdraw samples from research if the samples have not already been unlinked from the participant's identity.[8] Research using biorepositories continued quite adequately and effectively under this system. Now, these universities claim that they can keep the tissue of a person who has withdrawn consent and continue to use it for research. The harmful precedent is already evident. Research institutions that formerly adhered to the federal regulations and allowed participants to withdraw consent by withdrawing tissues have now determined they no longer have to follow this rule. Institutions that previously abided by the federal regulations are now arguing that they

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[7] Hogan & Hartson LLP, "Eight Circuit Clarifies Ownership of Research Specimens in *Washington University v Catalona*, Health Update, July 12, 2007, pp. 1-3 (www.hhlaw.com).

[8] RAND Corporation Report, "Case Studies of Existing Human Tissue Repositories Practices for Biospecimen Resource for Genomic and Proteomic Era," at 144.

no longer have to follow these regulations. Clearly their concern is not about protecting the participants and honoring their intentions, but rather about securing legal ownership of these samples for the institutions, and the resulting financial benefit.

***Us TOO International*** believes that this lamentable situation underscores why so many millions of people have legitimate concerns about the adequacy of their protection by federal and state laws and current organizational practices. Again, this case is a test of whether promises made by research institutions should be kept. The credibility of this nation's research establishment and commitment to the protection of human research subjects is at stake.

Patients, research participants and their families, such as those ***Us TOO International*** represents, have been turned into treasure troves and potential adversaries by research institutions. Already the news has gone forth to the research institutions that the federal regulatory ban on "exculpatory clauses" prohibiting research institutions from asking patients to waive any of their rights in informed consent forms ***was not even considered*** by the 8th Circuit in its decision.[9] 45 C.F.R. § 46.116. The 8th Circuit erred by not enforcing this provision which prohibits exculpatory language. The federal agency charged with

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[9] Hogan & Hartson LLP, "Eight Circuit Clarifies Ownership of Research Specimens in *Washington University v Catalona,* Health Update, July 12, 2007, pp. 1-3 (www.hhlaw.com).

protecting the rights of people who participate in research, the Office for Human Research Protections, has interpreted this provision to include language asking a participant to give up property rights in his tissue, including:

> "I voluntarily and freely donate any and all blood, urine, and tissue samples . . . and hereby relinquish all right, title, and interest to said items" and "By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research."

http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm.

If this Court does not take this matter up for further review, the 8th Circuit's affirmation of the Judgment will be used throughout the nation as a blueprint for the research institutions to shepherd unsuspecting research participants into the fold. Only too late will participants learn that they have lost control of how their bodily tissues can be used in research and that their unique tissues and DNA have become the property of the research institution immediately upon transfer - lock, stock and barrel - and could therefore be sold by the institution or used for any research the institution deems appropriate, regardless of the patient's express wishes.

The district court held that the only rights the patients kept was the right to not provide any more

samples in the future – which is to say, no rights at all. The 8th Circuit held that the patients did have the right to withdraw from research, but complete withdrawal from research without being able to transfer their samples would subvert the purpose of their wish to participate in prostate cancer research in the first place - research that might benefit them, their families, and other patients affected with their disease or similar diseases. Their only option besides letting the university perform whatever research it wants on their tissue – or selling it to a biotech company - according to the 8th Circuit is the choice of demanding the destruction of their tissue, precluding further research by Dr. Catalona – a sobering thought given that 6,000 people have already asked the university to transfer their tissue.

Research in this country is a big business.[10] Washington University has repeatedly emphasized the financial value of the patients' tissue in this case which it claims to be worth over $1 million. The research participants have no such financial interest in the case. They want research to go forward on their tissue for the benefits of themselves, their families, and future generations, as they were promised.

***Us TOO International*** fervently believes this case is not merely a narrow case of state property law, affecting only men from Missouri who requested

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[10] Washington University claimed net assets of over 5.7 billion dollars in its 2005 Form 990 (the latest form publicly available).

that their samples be transferred to Dr. Catalona. Rather, it is an issue of federal law as well as enormous national importance that affects the entire U.S. public, including the thousands of constituents of ***Us TOO International***. While only men are afflicted with prostate cancer, women are also affected by the disease, as it affects their life partners, their husbands, their fathers, brothers, and sons. All of the petitioners in this case are from states other than Missouri, yet the lower courts' Judgment applies to them just as it does to men in Missouri.

This case has been in the national spotlight, as the Petitioners have pointed out in their petitions and as noted below,[11] because the public has an intense interest in their own property rights and privacy, in the use of their bodily tissues in research, and in their rights and government-regulated

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[11] *See, e.g.*, Jocelyn Kaiser, Issues with Tissues, 316 *Science* 1829 (June 29, 2007); Jocelyn Kaiser, Biomedical Research: Court Decides Tissue Samples Belong to University, Not Patients, 312 *Science* 346 (April 21, 2006); Hakimian, R. & Korn, D., Ownership and Use of Tissue Specimens in Research, 293 *Journal of the American Medical Association* 1325-26 (March 16, 2005); Charo, R.A., Body of Research: Ownership and Use of Human Tissue, 355 *New England Journal of Medicine* 1517 (October 12, 2006); Goldman, Michael A., Calamity Gene, 445 *Nature* 819-820 (2007); Andrews, Lori, Who Owns Your Body? A Patient's Perspective on *Washington University v. Catalona*, 34 *Journal of Law, Medicine & Ethics* 398-407 (2006); Cheryl W. Henaver, Court: University Owns Research Samples, *USA Today*, June 22, 2007; Crichton, Michael, Opinion, Body Snatchers, 2006, *Wall Street Journal*, December 15, 2006; Rebecca Skloot, Taking the Least of You, *New York Times Magazine*, April 16, 2006.

protections in their research partnerships with institutions.

All research institutions have an avid, vested interest in the outcome of this case, as they can rely on the 8th Circuit court's Judgment to lay ownership claims to samples collected by unwitting participants at their own institutions. However, federal regulations and the Common Rule require that samples provided by research participants may be used only in institutional board-approved research protocols that have been fully explained to the participants, and then only after informed consent has been ***voluntarily*** given. Both the research protocols and informed consent documents are governed by federal regulations, and all research institutions that receive federal funds, such as Washington University, must comply with them. 46 C.F.R. § 46.116.

These governing federal regulations are in direct conflict with the 8th Circuit's judgment. If the patients and research participants cannot turn to the federal courts to enforce federal regulations promulgated for their protection in human research studies, to whom can they turn?

Another important aspect of the samples being linked to an individual person and thus being personally identifiable[12] is particularly important to ***Us TOO International***. We believe that, especially in the emerging era of personalized medicine, it is vital that patients retain some control of how their tissues

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[12] Tr 1 at 69-70; Tr 2, at 112-113.

are used in research.[13] Medications are being developed which are only recommended for people with a specific genetic makeup or whose cancerous tumors had a specific genome. Anonymizing the research participants' tissue or forcing them to order it to be destroyed ruins this opportunity.

Our support extends not only to the victims of prostate cancer but also their families who might someday benefit from the knowledge of the particular genetic mutation which caused a relative's cancer. People provided their tissue for Dr. Catalona's research because they were told it would benefit their families. It is imperative that genetic research on tissue samples be used to alert "members of [a patient's] family who are at high risk of developing prostate cancer." In the consent forms signed by the patients and research participants in this case, one of the "potential benefits" listed was the ability to notify, where appropriate, patients' families of such risks. This benefit could only be realized by keeping the tissue samples traceable to their source.[14]

As a policy, the position of this friend of the court is: legally and ethically, the patient - not the university or researcher - must have the ultimate say concerning the use of his bodily tissues in research. ***Us TOO International*** believes that having the Courts protect patients' rights in their relationship with the biomedical research establishment, under federal regulations and the

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[13] Tr. 1 40 and Tr. 2, 126-130.
[14] Tr. 2 at 130.

Common Rule, is crucial to ensure their willingness to participate in research.

***Us TOO International*** is strongly committed to the proposition that, concerning choices about disease prevention, early detection, treatment, or participation in research, the patient's interests should come before the interests of any institution or practitioner. While the institution or practitioner has the responsibility to fully inform the patient about the potential risks, benefits and other implications of such choices, based on the full spectrum of evidence, any decisions about participation and its scope must remain with the patient.

In clear conflict with the federal regulations and patients' rights, the federal district court's rejection of this fundamental principle of human subjects research is of compelling national importance to merit its review by the Supreme Court.

When research participants volunteer and sign agreements as to their understanding of what will be done with their bodily tissues, their wishes as reflected in these agreements should be respected and honored by the institutions and researchers collecting specimens and by the courts. As the 8th Circuit failed to apply federal law appropriate to this case, the Supreme Court should review this matter.

## CONCLUSION

WHEREFORE, for all the foregoing reasons, ***Us TOO International*** respectfully requests that this court grant the petitions of the petitioners for a writ of certiorari.

Respectfully submitted,

Robert S. Adler
ROBERT S. ADLER, PC
7777 Bonhomme Avenue
Clayton, Missouri 63105
(314) 725-2400
(314) 725-2405 (facsimile)
*Counsel for Amicus Curiae*
*Us TOO, International*